

Decreased bone density of the distal femur after uncemented knee arthroplasty

A 1-year follow-up of 29 knees

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We measured the early adaptive bone remodeling of the distal femur prospectively for 1 year after uncemented total knee arthroplasty (TKA) in 29 knees with primary arthrosis. 18 patients were randomized to receive a PCA Modular[®] femoral component (n 9) or a modified version of the same prosthesis (n 9) with an altered location of the porous coating. The other 11 patients (n 11) formed a consecutive series with the Duracon[®] femoral component. In the trabecular bone above the femoral component, bone mineral density (BMD) was measured in 2 regions of interest (ROI) anteriorly to the fixation pegs (ROI 1) and above the pegs (ROI 2), using dual photon absorptiometry (DPA). There were no differences between the Modular component and the modified version

regarding the postoperative decrease in BMD. There was a decrease in BMD in both ROI 1 and ROI 2 with all 3 different femoral components, and in both ROIs the highest bone loss rate was observed during the first 3 months after surgery. On average (n 29), a significant bone loss of 44% and 19% in ROI 1 and ROI 2, respectively, was reached at the 1-year follow-up, compared to the initial values. A decrease of this magnitude in BMD in the anterior distal femur 1 year after TKA may be an important determinant of periprosthetic fracture and later failure of the femoral component. In this experimental set-up, a modified femoral component with an altered location of the porous coating did not influence the development of bone loss.

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A bone adjusts its density and structure to the current mechanical demands. A total joint replacement may lead to a significantly altered stress distribution pattern in the bones, as shown in studies using finite element analysis (Huiskes et al. 1987, Orr et al. 1990, Tissakht et al. 1993). Adaptive remodeling with local bone loss has previously been observed in total hip arthroplasty (THA) (Brown and Ring 1985, Engh et al. 1987), total knee arthroplasty (TKA) (Cameron and Cameron 1987, Mintzer et al. 1990, Petersen et al. 1995b), spinal fixation (McAfee et al. 1989, Smith et al. 1991, Dalenberg et al. 1993) and rigid metal plating (Terjesen and Benum 1983, Uthoff et al. 1994). This implant-related osteopenia is considered to be mainly a result of stress-shielding, but immobilization, in combination with a local reaction of the tissue to the operative trauma itself, may play a role as well (Frost 1983). In two retrospective radiographic studies, qualitative loss of bone mineral in the distal anterior femoral condyle following TKA has been described (Cameron and Cameron 1987, Mintzer et al. 1990), but only 2 previous studies have quantitated these changes (Petersen et al. 1995b, Liu et al. 1995). We measured the early adaptive changes in bone min-

eral density (BMD) of the distal femur following uncemented TKA, and evaluated the influence on bone density of altered location of the porous coating in a femoral component.

Patients and methods

24 patients with primary arthrosis of the knee were randomized to receive either a standard femoral component (PCA Modular[®], Howmedica) or a modified version of the same component specially designed for this study. The PCA Modular component had a surface designed to obtain permanent fixation by bone ingrowth with the total surface covered with a porous coating, except on the surface of the 2 fixation pegs. The modified component had an altered location of the porous coating, but was otherwise identical with the standard component. The porous coating was removed from the anterior and posterior flanges and coating was added to the surface of the pegs. During follow-up, 6 patients were excluded from the study: 2 died and 2 were unable to attend all controls because of poor health, 1 refused to participate after inclusion

Table 1. Clinical data in 29 patients

| | Femoral component | | |
|------------------------------|-------------------|------------------|------------|
| | Modular | Modified Modular | Duracon |
| <i>Patients</i> | | | |
| n | 9 | 9 | 11 |
| Age | 70 (59–79) | 74 (63–83) | 69 (51–81) |
| Female/male | 7/2 | 8/1 | 4/7 |
| <i>HSS score^a</i> | | | |
| Preop. | 61 (51–71) | 57 (40–72) | 57 (39–69) |
| 1 year | 89 (80–93) | 89 (69–96) | 81 (61–94) |

^a No difference in HSS score (preoperatively, at 1 year or the increase between the two) between different femoral components.

and initial measurements and 1 patient was excluded because of poor quality of the BMD-measurements. Thus 9 patients with the standard prosthesis and 9 patients with the modified femoral component were left for the study. Furthermore, 11 consecutive patients with primary arthrosis operated on with insertion of TKA, using another standard porous-coated femoral component (Duracon[®], Howmedica) were studied (Table 1). All operations were performed without bone cement, as described by Hungerford et al. (1982), and using the same type of tibial component (PCA Modular[®]). The clinical outcome of the operations was evaluated by the Hospital for Special Surgery knee-rating score (HSS knee-score; Insall et al. 1976).

BMD (g/cm²) in the mediolateral plane of the distal femur was measured by dual photon absorptiometry (DPA) using a custom-made knee scanner (GT-50, Femur-1a, Gammatec A/S, Stormly 16, DK-3500, Værløse, Denmark) with Gadolinium-153 (200mCi) as a photon source. The scanner uses the radiation peaks of 44 and 100 KeV from a Gadolinium-153 source with maximum activity of 200 mCi (half-life 242 days). The detector of the DPA-system consists of a NAI-detector with a 3-channel system: 1 channel for 44 KeV and 2 channels for 100 KeV with automatic peak control. The diameter of the active beam size at the bone was 4 mm, and the distance between the photon source and the detector was 20 cm. To obtain reproducible scanning statistics, the scan speed

(4–6 mm/s) was automatically adjusted according to the decay of the source, and scanning was performed with a spatial resolution (pixel size) of 2 × 2 mm². On the computerized scan plot of the distal femur, 2 regions of interest (ROI) were selected for measurement of BMD (Figure 1). To obtain the best obtainable precision throughout the study period with 4 measurements in each patient, the ROIs selected were often larger and not identical with those used in our previous study (Petersen et al. 1995b), and the small ROI located behind the fixation pegs was not used in the present study. The actual size of each ROI was determined by the dimensions of the femoral bone and ROIs of 1.0 × 1.0 cm² (25 pixels) or 1.2 × 1.2 cm² (36 pixels) and seldom of 1.4 × 1.4 cm² (49 pixels) were used. The initial size of a ROI in a patient was kept the same throughout the study. The patients were scanned postoperatively within 8 weeks after the operation and after 3, 6 and 12 months. The precision was evaluated from BMD double measurements in 12 patients with unilateral uncemented TKA, using each type of femoral component in four patients. This study has been approved by the local ethics committee and informed consent was obtained from the patients.

Statistics

The precision was expressed as the coefficient of variation (CV = (SD/mean) × 100%). Nonparametric tests for unpaired data (Mann-Whitney) and two-way analysis of variance (Friedman) were used. P-values below 0.05 were considered significant. Statistical power analysis with calculation of the probability of type 2 error was performed with a fixed type 1 error probability of 5%.

Results

The clinical outcome was similar for the 3 femoral components (Table 1). The mean precision error for repeated measurements of BMD was 3.2 (0.0–7.3)% and 2.2 (0.0–4.6)% for ROI 1 and ROI 2, respectively. No statistical differences between the 2 randomized groups were found regarding the baseline values of

Figure 1. Scan plots of the distal femur after implantation of TKA, showing the location of the two ROIs selected for the BMD-measurements distally behind the anterior flange of the femoral component (ROI 1) (left) and above the fixation pegs (ROI 2) (right).

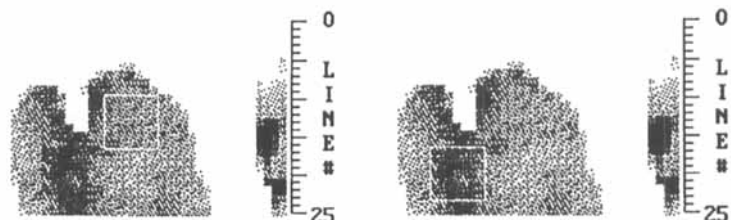


Table 2. Comparison between the 3 groups (with different femoral components) regarding baseline values for BMD measurements (g/cm²)

| Initial BMD measurement | Femoral components | | |
|-------------------------|--------------------|------------------------|------------------|
| | Modular (n 9) | Modified Modular (n 9) | Duracon (n 11) |
| Days after surgery | 22 (6–48) | 14 (6–24) | 32 (3–56) |
| Anterior region (ROI 1) | 0.95 (0.63–1.30) | 0.71 (0.28–1.00) | 1.17 (0.50–2.05) |
| Proximal region (ROI 2) | 1.34 (0.61–1.88) | 1.23 (0.75–1.73) | 1.60 (0.73–2.32) |

Table 3. Comparison of the changes in BMD (g/cm²) in the randomized study with the two Modular femoral components. BMD changes are given as mean (total range)

| BMD, months | Femoral components | | |
|--------------------------------|----------------------|------------------------|----------------------|
| | Modular (n 9) | Modified Modular (n 9) | P-value ^a |
| <i>Anterior region (ROI 1)</i> | | | |
| 0–3 | 0.29 (–0.06 to 0.53) | 0.14 (0.01 to 0.42) | 0.09 |
| 3–12 | 0.09 (–0.02 to 0.22) | 0.14 (–0.19 to 0.61) | 0.69 |
| 0–12 | 0.38 (0.00 to 0.74) | 0.28 (0.00 to 0.77) | 0.20 |
| <i>Proximal region (ROI 2)</i> | | | |
| 0–3 | 0.16 (–0.08 to 0.57) | 0.16 (–0.16 to 0.55) | 0.79 |
| 3–12 | 0.09 (–0.09 to 0.31) | 0.09 (–0.09 to 0.35) | 0.96 |
| 0–12 | 0.25 (–0.17 to 0.56) | 0.25 (–0.11 to 0.66) | 0.83 |

^a Mann-Whitney test

the BMD measurements or the time postoperatively until the initial scanning. The baseline values of BMD in ROI 1 of the Duracon femoral component differed ($p = 0.02$) from the initial BMD values in the patients with the modified Modular femoral component (Table 2). In the randomized study, a tendency towards a lower early bone loss rate in ROI 1 in the patients with the modified femoral component was seen. No difference between the Modular component and the modified version regarding the decrease in BMD at the 1-year follow-up was observed (Table 3). The bone loss rates in ROI 2 were identical in the 2 different Modular femoral components. BMD in ROI 1 decreased with time for all 3 different femoral components (Modular; $p = 0.002$, modified Modular; $p = 0.0005$, and Duracon $p < 0.00005$), and the same bone loss pattern, although less pronounced, was seen for the measurements in ROI 2 (Modular; $p = 0.05$, modified Modular; $p = 0.01$, and Duracon $p < 0.00005$) (Figure 2). In both ROIs, the highest bone loss rate was observed during the first 3 months after the operation (Figure 2). On average ($n = 29$) a significant bone loss of 44% ($p < 0.00005$) and 19% ($p < 0.00005$) for ROI 1 and ROI 2, respectively, was observed at the 12-month follow-up, compared to the initial values (Figure 3).

Discussion

The mean precision of 3.2% and 2.2% for measurements of BMD in ROI 1 and ROI 2, respectively, in this study was slightly higher than the precision obtained in a previous study, using the same DPA-scanner (Petersen et al. 1995b) and in a methodological study, using dual-energy X-ray absorptiometry (DEXA) (Robertson et al. 1994). In our previous study (Petersen et al. 1995b), the precision was evaluated in only 3 patients and may be considered the best obtainable precision with this scanner, when measurements are performed under optimal conditions. In the DEXA study (Robertson et al. 1994), the average precision for measurements of BMD in the anterior distal femur was 1.2 (0.1–3.0)%. All scanings were performed on one cadaver femur with a set-up which allowed controlled changes in density of the ROI, and with identical rotation between measurements, which were performed at a constant soft-tissue thickness.

Previous finite element models of the distal femur following TKA (Walker et al. 1982, Tissakht et al. 1993) have shown, that the strain in the anterior distal femur is altered from a high-stress region to a stress-shielded region following implantation of the TKA. The bone loss is expected to occur especially in the

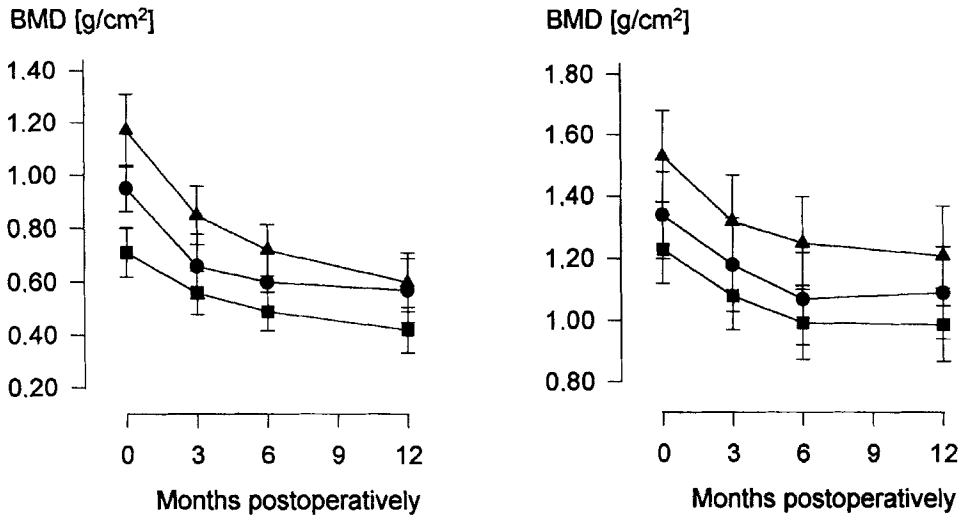


Figure 2. Changes in BMD (mean and standard error of the mean) in ROI 1 behind the anterior flange (left) and in ROI 2 above the fixation pegs (right) of 3 different femoral components. Modular ● (n 9), modified Modular ■ (n 9), and Duracon ▲ (n 11).

anterior distal femur, and the highest degree of stress-shielding could be expected if the anterior and posterior flange surfaces are bonded to the bone (Walker et al. 1982, Tissakht et al. 1993). If the anterior and posterior surfaces are not bonded to the bone, some load transfer through the distal anterior femur should be possible, and thus stress-shielding leading to the development of bone loss might be avoided. A study by Whiteside and Pafford (1989) indicated that a porous-coated femoral component with smooth anterior and posterior flange surfaces could prevent the radiologi-

cal appearance of stress-shielding, and most knees even showed a hypertrophic pattern of the trabecular bone in the anterior distal femur. However, no quantitative measurements of bone density were performed in that study.

Our findings support the bone loss pattern behind the anterior flange of the femoral component following TKA, which was suggested by previous radiographic studies (Cameron and Cameron 1987, Mintzer et al. 1990). The decrease in femoral BMD we found was significantly higher than the average decrease of 8% below the tibial plateau 1 year after TKA (Petersen et al. 1995a), and also previous prospective studies using DEXA for measurements of BMD around cemented or uncemented femoral components after total hip arthroplasty (Cohen and Rushton 1995, Kiratli et al. 1996) have shown a postoperative bone loss less than what was seen in the present study.

In our randomized study, no significant effect of the modified porous coating on the bone mineral density was found. The early bone loss (0-3 months) and total bone loss (0-12 months) in ROI 1 were less than that seen in femurs with the nonmodified modular femoral component implanted, while the decrease in BMD in ROI 2 was about the same in the two groups. No large preventive effect of the modified femoral component regarding bone loss in ROI 1 was detected. If the early bone loss (0-3 months) in ROI 1 was totally prevented by the modified femoral component, the number of patients needed in each group to reach a type 2 error of 10% or 5% was 9 and 12, respectively. If the early difference of 0.15 g/cm² actually found in our study was used as the minimal relevant difference be-

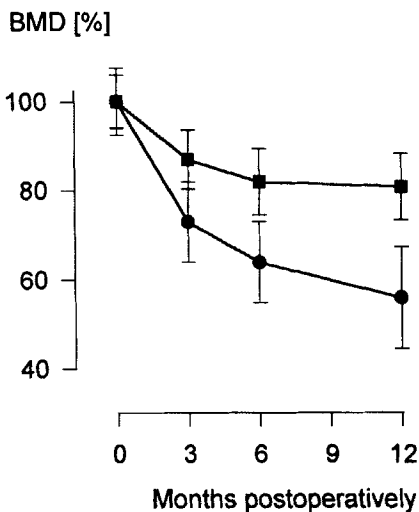


Figure 3. Percentage changes in BMD (mean and standard error of the mean) behind the anterior flange (ROI 1 ●) and above the fixation pegs (ROI 2 ■) for all femoral components (n 29).

tween groups with 9 patients in each group, the type 2 error was 63%. If statistical power calculations were performed using the total change in BMD (0-12 months) as the relevant parameter, the type 2 error increased to 85%. Thus the altered porous coating could not completely prevent bone loss in ROI 1, but a smaller preventive effect could not be evaluated in this study because of the lack of sufficient statistical power to detect a relatively small difference in adaptive bone loss patterns between the prostheses.

As regards all 29 femoral components, a significant bone loss 1 year after surgery of, on average, 44% and 19% for ROI 1 and ROI 2, respectively, was seen. These findings are in agreement with our previous study (Petersen et al. 1995b), considering that the baseline measurements in our earlier study were not performed as close to the time of surgery as in the present study, and thus the initial and very fast bone loss, probably induced by the operative trauma, was not determined. Liu et al. (1995) measured BMD changes in the distal femur, following uncemented TKA using DEXA, but only one of their ROIs was similar to ours. In the ROI comparable to our ROI 2, an average decrease of 18% in BMD was seen 6 months postoperatively, followed by a partial remineralization. Thus the total bone loss after 1 year was only 8%. In our study, the decrease in BMD after 6 months was on the same level as in the study by Liu et al. (1995). However, no remineralization was observed at the 1-year follow-up. A possible explanation of this difference in remineralization between the studies could be that the mean age of the patients in the study by Liu et al. (1995) was 6 years less than that of patients in our study, thus allowing a better rehabilitation with a higher level of physical activity to be reached after the operation.

Generally, the long-term results following TKA are quite satisfactory, with a low revision rate (Knutson et al. 1994). Supracondylar fractures of the femur following TKA are rare (Nielsen et al. 1988, Figgie et al. 1990), but are difficult to treat (Nielsen et al. 1988, Figgie et al. 1990, Garmavos et al. 1994). It is well known that there is a close relation between BMD and the strength of trabecular bone (Hvid et al. 1985, Strømsøe et al. 1994) and, theoretically, an increased risk of periprosthetic fractures or loosening of the femoral component might be expected in patients with a high postoperative bone loss.

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